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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 1001.1708101

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Application Number	Filed
10/667,056	September 22, 2003

First Named Inventor: Sean McFerran

Art Unit	Examiner
3767	Philip A. Gray

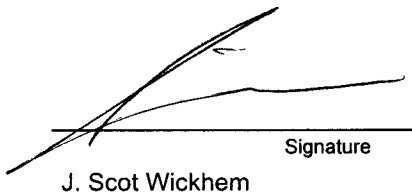
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 41,376.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____



Signature

J. Scot Wickhem

Typed or printed name

612-677-9050

Telephone number

1-13-2011

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Sean McFerran	Confirmation No.:	7830
Serial No.:	10/667,056	Examiner:	Phillip A. Gray
Filing Date:	September 22, 2003	Group Art Unit:	3767
Docket No.:	1001.1708101	Customer No.:	11050
For:	MICROCATHETER WITH SLEEVED GUIDEWIRE PORT		

Mail Stop Appeal
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 13th day of January 2011.

By _____
Kathleen L. Boekley

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 13, 15-17 and 21-28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Pfenninger (U.S. Patent No. 5,306,247) in view of Allman et al. (U.S. Patent No. 6,346,093. Neither Pfenninger nor Allman et al., taken alone or in combination, appear to teach or suggest the microcatheter structure recited in independent claim 13. The rejection is thus an error. In response to Applicant's previous arguments that both Pfenninger and Allman et al. do not appear to teach or suggest "wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft", the Examiner asserts:

> Examiner is reading this limitation as a functional/operational limitation. The same reading of the limitation for claim 27 (since the "passage is configured to..") is being read as a functional limitation. Therefore the limitation is not a positive limitation but only requires the ability to so perform. Further the "wherein" statement does not define any structure and accordingly can not serve to distinguish. The examiner is of the position that Allman would teach this fluid tight abilty when no guide wire is in the passageway. Evidence of this can be found at Allman paragraphs at column 2 lines 60 through column 3 line 22;

> column 8 lines 1-47; and column 10 line 62 through column 11 line 52, and further see slit and sheaths shown in figures 3-8.

Applicant respectfully disagrees with the Examiner's assertion that Allman et al. disclose the lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft. Allman et al. disclose at column 3, lines 1-7, "The elongate shaft includes a proximal guidewire port disposed between the proximal end of the shaft and the distal guidewire port to facilitate single operator use. A seal may be disposed adjacent the proximal guidewire port to thereby seal the port. Preferably, the seal provides a fluid seal with or without the guidewire disposed therein." As can be seen, Allman et al. appear to disclose the shaft includes at least two guidewire ports, a proximal guidewire port and a distal guidewire port. Allman et al. further appear to disclose that only the proximal guidewire port includes a seal disposed adjacent thereto. Allman et al. appear to be silent with respect to the distal guidewire port. Applicant submits that a reference being silent regarding a structure cannot be deemed to positively teach that structure. Furthermore, column 8, lines 1-47 and column 10, line 62 through column 11, line 52, which the Examiner relies on as disclosing the claimed limitation appear do not appear to teach or suggest "when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft," as currently claimed. Rather, the cited passages appear to disclose a sheath assembly which may used to constrain guidewire movement. With respect to the disclosed sheaths, Allman et al. disclose at column 7, lines 43-54:

> For this reason, when larger endoscope working channels are used, an exchange sheath having a sufficiently small inner diameter so as to constrain guidewire movement to within the catheter U-channel 42 is employed with the preferred embodiment. Generally speaking, an endoscope exchange sheath in accordance with the preferred embodiment allows for use of a radially accessible guidewire, which is longitudinally aligned with the catheter, while presenting a circular profile to an endoscope and mitigating guidewire pinching problems between the catheter and the endoscope working channel wall.

Nowhere do Allman et al. appear to teach or suggest the sheath is configured to provide a substantially fluid tight seal as the Examiner appears to be asserting. Further, nothing in the structure of the sheath of Allman et al. appears to indicate the sheath would provide such a seal.

In response to Applicant's previous arguments, the Examiner further asserts:

> Further is it examiners position that both Pfenninger and Allman discloses "a slit extending at an angle such that the slit has a depth measured from the inner

> surface to the outer surface of the polymer sheath that is greater than the thickness of the wall of the polymer sheath, wherein the slit is defined between a first edge of the polymer heath and a second edge of the polymer sheath facing the first edge, wherein each of the first edge and the second edge extend from the outer surface to the inner surface of the polymer sheath, and wherein the first edge and the second edge are in contact with each other when no guidewire is extended through the passage". Both Pfenninger and Allman teach this as would any slit on an angle less then 90 degree to the outer surface (see Pfenninger figure 3 and Allman figure 4B or 4C).

Applicant respectfully disagrees. Pfenninger appears to disclose a balloon catheter including an inflation lumen and a guidewire lumen. The guidewire lumen and inflation lumen appear to be disposed coaxially within the proximal portion of the catheter shaft and side-by-side in the distal portion of the catheter shaft. Pfenninger further appears to disclose the catheter shaft may include an opening disposed in the side of the catheter shaft for receiving the guidewire into the guidewire lumen at a location distal of the proximal end. The catheter shaft appears to include an outlet opening (9) for receiving the guidewire. As can be seen in Figure 4 of Pfenninger, the opening appears to be a relatively large hole in the catheter shaft. Pfenninger appears to disclose the outlet is formed at the distal end of the proximal portion of the catheter shaft. The outlet appears to be disposed through the wall of the guidewire lumen as well as the wall of the proximal portion of the inflation lumen. In formulating the rejection, the Examiner appears to be asserting a sidewall of the opening of Pfenninger to be equivalent to the presently claimed slit. Applicant respectfully disagrees.

As can be seen, the passage in the sheath as currently claimed comprises an angled slit. As one of ordinary skill in the art may be well aware, a slit is commonly used to define a narrow cut or opening. For example, Merriam-Webster defines slit as "a long narrow cut or opening" (http://www.merriam-webster.com/dictionary/slit, accessed July 2, 2010). The intended meaning of the word slit is further evidenced by the description as well as the figures. See, for example, Figure 7 of the present application. Furthermore, the Examiner appears to assert that because the side wall of the outlet of Pfenninger is angled, Pfenninger discloses an angled slit. Clearly, an angled wall cannot be equated to the presently claimed slit. Furthermore, as can be seen in Figure 3 of Pfenninger, there appears to be no structure capable of providing a substantially fluid tight seal when no guidewire is present.

Moreover, Allman et al. do not appear to teach or suggest an angled slit as the Examiner appears to be suggesting. The Examiner references Figures 4B and 4C of Allman et al. as allegedly illustrating an angled slit. Applicant respectfully disagrees. The slit, as illustrated by Allman et al. appears to be at 90 degrees. Allman et al. do not appear to teach or suggest otherwise.

The Examiner appears to be relying on Allman et al. as disclosing the structure necessary to provide a substantially fluid tight seal. In formulating the rejection, the Examiner asserts, "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly." Applicant respectfully disagrees. Pfenninger appears to disclose the outlet (oblong hole) is an advantageous structure. For example, Pfenninger disclose at column 7, lines 39-45, "The shape of the cutout thus produced does not lead to any stress peaks in the catheter shaft. This cutout shape may be so large and so long that guide wire 8 easily comes out of shaft 1 when threaded into the catheter without requiring devices such as a ramp, etc., in lumen 7 to facilitate the catheter coming out of the shaft." Thus it is unclear why one would be motivated to change the shape or type of opening in the shaft of Pfenninger. Furthermore, Allman et al. appear to disclose the sheath including the slit is disposed over a catheter assembly in order to maintain the guidewire within the lumen. If one were to modify the device of Pfenninger to include the sheath of Allman et al. over the catheter shaft (as currently claimed), as suggested by the Examiner, Applicant respectfully asserts the device of Allman et al. would not function as intended. MPEP 2143.01 V states, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)."

Therefore, for at least these reasons, neither Pfenninger nor Allman et al., taken alone or in combination appear to teach or suggest the microcatheter as currently claimed. Thus, even if one were to combine Pfenninger and Allman et al., one would not arrive at the device as claimed. Furthermore, there appears to be no motivation, suggestion or other reason for one of ordinary skill in the art to modify Pfenninger or Allman et al. to arrive at the device as claimed. The

rejection is thus an error. Reconsideration and withdrawal of the rejection are respectfully requested. For similar reasons, as well as others, independent claim 27 is also believed to be patentable over Pfenninger and Allman et al. Applicant submits that claims 15-17, 21-26, and 28 are also in condition for allowance as they depend from one of claims 13 or 27 and add significant limitations to further distinguish them from the prior art.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Sean McFerran

By his Attorney,

Date: 1-13-2011

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